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UK Merger Control

The UK Competition and Markets Authority Breaks New Ground in Asserting Jurisdiction Over Mergers With no Effects in the UK

SUMMARY

The UK Competition and Markets Authority's ("**CMA**") review and clearance of the proposed acquisition by Roche Holdings, Inc. ("**Roche**") of Spark Therapeutics, Inc. ("**Spark**") on 10 February 2020 is the latest example of the CMA scrutinising a merger with no obvious jurisdictional link to the UK.

The case exemplifies how the CMA has started using the "share of supply test" as an all-purpose tool to assert jurisdiction over mergers — even when the target has no sales in the UK. Coming shortly after the CMA's prohibition of the proposed acquisition by Illumina, Inc. ("**Illumina**") of Pacific Biosciences of California, Inc. ("**PacBio**"), and given the CMA's ongoing investigation of Sabre Corporation's ("**Sabre**") proposed acquisition of Farelogix, Inc. ("**Farelogix**"), Roche/Spark further demonstrates the CMA's willingness to apply the share of supply test creatively to assert jurisdiction over mergers in which the target has little or no UK market presence. This is particularly likely when the target is a potential market entrant in the UK and the CMA considers its intervention necessary to preserve what it has termed "actual potential competition".

The Roche/Spark case is a strong reminder of the CMA's broad review powers under the share of supply test, its willingness to assert jurisdiction over mergers, even on the basis of reasoning that may appear fanciful, and its keen interest in so-called "nascent competitors" — especially in the pharmaceutical and technology sectors.

THE ROCHE/SPARK TRANSACTION

On 22 February 2019, the global biotechnology company Roche agreed to acquire U.S.-based Spark for $4.3 billion. Both companies are active in the prophylactic treatment for congenital Hemophilia A, a rare genetic condition that manifests in insufficient or deficient clotting factor which impairs the patient's ability to form blood clots and stop bleeding. Roche manufactures and supplies emicizumab, sold under the brand name Hemlibra, which is administered subcutaneously and mimics the clotting factor in a patient in order to prevent or reduce bleeding. Spark, on the other hand, has not yet commercialised

any treatment for Hemophilia A. It is currently developing a gene therapy treatment based on SPK-8011 and SPK-8016, which are still in the development phase. In contrast to Roche's Hemlibra, Spark's gene therapy treatment would involve a one-time administration which, if successful, would allow patients to start producing their own clotting factor.

Roche did not notify the transaction to the CMA. This is understandable because Spark's absence from the market in the UK would have given Roche good reason to conclude that the CMA lacked jurisdiction to review the transaction. However, on 11 June 2019, the CMA issued an initial enforcement order ("**IEO**"), preventing the parties from integrating the two businesses prior to CMA clearance. The CMA formally launched its merger inquiry on 22 October 2019. On 16 December 2019, the CMA cleared the transaction on the basis that Spark would not be the only supplier developing a gene therapy treatment for Hemophilia A, and that Spark's pipeline product could not be considered to have any particular advantages over those developed by other suppliers.

ANALYSIS

Expanding the Share of Supply Test

Under the Enterprise Act 2002, the CMA has jurisdiction to review mergers if the target's UK turnover meets certain thresholds,[1] or alternatively, if the parties have overlapping activities in the UK and have a combined "share of supply" in the UK (or in a substantial part of the UK) of 25% or more in the supply or acquisition of goods or services of any description (the "share of supply test").

Given that Spark generated *no* turnover in the UK in 2018, the CMA could not assert jurisdiction on the basis of the turnover threshold described above. However, stressing its "broad discretion to choose a specific category of goods" for the purposes of the share of supply test,[2] and that it was entitled to "apply this rule in a flexible and purposive way" to find a link to the UK,[3] the CMA asserted a jurisdictional link by Spark to the UK, and therefore concluded that it had jurisdiction over the merger.

The CMA carried out an unusually detailed (43 paragraphs) and creative analysis of whether the parties met the share of supply test. It concluded that notwithstanding that Spark had not yet commercialised any of its pipeline products (and had zero sales or revenue in the UK), it was "active in the supply of" Hemophilia A treatments in the UK. The CMA justified this conclusion on the basis of the "commercial realities of the pharmaceutical sector", and given that R&D is integral "along with activities such as marketing and selling" to the process of supplying pharmaceutical treatments — regardless of the fact that Spark had no actual sales in the UK and that its two pipeline products were at a very early Phase I/II stage, respectively. On the basis that Spark's global R&D activities "form an integral part of the

1 £70 million, unless the target is involved in the development or production of "restricted goods", and certain computing-related activities within the meaning of section 23A of the Enterprise Act 2002, in which case the threshold for the target's turnover drops to £1 million (section 23(1) of the Enterprise Act 2002).

2 Paragraph 76 of the CMA decision in Roche/Spark.

3 Paragraph 77 of the CMA decision in Roche/Spark.

process of making the treatment available in the UK", that its employees are undertaking R&D activity in the UK, and the fact that some of Spark's patents are registered in the UK,[4] the CMA concluded that there was a sufficient jurisdictional link to the UK under the share of supply test.

In addition to its inventive approach to the geographic connection of Spark's R&D activities to the UK, the CMA considered that gene therapy and non-gene therapy treatments should be considered together as one "relevant product" for the purposes of the share of supply test. This allowed the CMA to take into account Roche's non-gene therapy sales, notwithstanding the lack of increment in its share following its acquisition of Spark, given that Spark generated no turnover in the UK. The CMA noted — boldly — that "the Act gives a wide discretion to the CMA to apply whatever measure, or combination of measures, it considers appropriate to calculate the merging parties' share of supply or procurement and to determine whether the 25% threshold is satisfied […] the CMA shall apply such criterion as it considers 'appropriate'".[5] In this case, the CMA considered it "appropriate" to use the number of UK-based employees engaged in non-gene and gene therapy Hemophilia A R&D as the metric to determine whether Roche and Spark's combined "share of supply" exceeded the 25% threshold. On that basis, it estimated that Roche and Spark would have a combined share of 40%-50% with an increment of 5%-10% as a result of the merger.

As a separate basis for asserting jurisdiction under the share of supply test, the CMA concluded that Roche and Spark exceeded the 25% threshold on the basis of the number of UK patents procured in relation to the treatment of Hemophilia A generally available.

In summary, the CMA chose liberally: (i) the basis for "commercial activity" flowing from Phase I and II stage trials; (ii) the geographic nexus to the UK on the basis of *global* R&D activities; and (iii) the criteria to define both the "relevant product" (non-gene and gene therapy Hemophilia A treatments) and the metric to calculate the share of "supply" (employees engaged in R&D related to Hemophilia A and the number of UK patents procured).

Roche/Spark is only the most recent example of a broader trend. On 24 October 2019, the CMA published its provisional findings of its review of the proposed Illumina/PacBio acquisition, which ultimately hinged on the basis of the miniscule increment of share of supply of DNA sequencing systems that Illumina would gain as a result of its acquisition of PacBio (0%-5%). This is even more remarkable, given that the CMA's provisional findings effectively amounted to a provisional prohibition of the transaction, which led the parties to that transaction to abandon the merger on 2 January 2020.

Similarly, in its recent decision to investigate the proposed acquisition by Sabre of Farelogix, stressing the "public importance" attributed to its role in effectively regulating merger activity, the CMA found the share of supply test to be satisfied merely by the parties' sales to a *single* customer in the UK (British Airways), and on the basis of "two-sided features" of supply of certain services. This was the case

4 *See* paragraph 94 of the CMA decision in Roche/Spark.

5 *See* paragraph 105 of the CMA decision in Roche/Spark.

notwithstanding that the target had *no* customers in the UK. This illustrates how the share of supply test gives the CMA almost limitless scope to define categories of goods and services and choose metrics in order to satisfy the jurisdictional share of supply test by proving an overlap and combined share of supply exceeding the 25% threshold.

Heightened CMA Scrutiny May Have Onerous Consequences for Merging Parties

The CMA's trend of liberally asserting jurisdiction is likely to continue going forward, especially in light of the CMA's ambition to position itself as a prominent competition authority after the UK exits from the EU. This is likely to have onerous consequences for merging parties.

First, the CMA review process is frequently lengthy and burdensome for merging parties and may cause them to significantly delay closing their merger. Under the merger agreement in Roche/Spark, Roche's offer for Spark was originally scheduled to expire on 10 December 2019. In order to provide additional time for the FTC and CMA to complete their reviews, Roche and Spark extended the offer period until 16 December 2020. Similarly, in Illumina/BioPac, the parties originally intended to consummate the merger around 31 November 2019, but extended the completion date to 31 December 2019, and then to 31 March 2020, in order to accommodate the CMA and the FTC review timeline.

Second, the CMA's IEOs can be very damaging for acquirers, allowing closing but requiring that the parties be held separate and integration be frozen until the CMA clears the transaction. 2019 saw heightened enforcement action for breach of IEOs, illustrating that the CMA is actively monitoring and willing to sanction non-compliance.[6]

Lastly, the CMA has, and uses, powers to force the unscrambling of completed mergers if it concludes that a less drastic remedy will be ineffective, or if the completed merger would prejudice its review. Recent examples include the CMA's unwinding order in Bottomline Technologies/Experian of 6 August 2019, and in Tobii/Smartbox of 26 April 2019.

Innovation, Nascent Competition and the Pharmaceutical Sector

Although Roche and Spark are not actually currently competing, given that Spark's gene therapy products are still in the development phase, the CMA placed significant emphasis on the "commercial reality" that both parties had altered their commercial strategies in order to compete against each other, and against other firms with marketed *and* pipeline products. This exemplifies the CMA's increased scrutiny of so-called "nascent competition", which played a prominent role in its provisional findings of prohibition in Illumina/PacBio and mirrors the CMA's Chief Executive Coscelli's statements in a speech to the OECD/G7 conference on competition and the digital economy on 3 June 2019, in which he remarked that "the elimination of even a very small or nascent competitor could remove an important

[6] *E.g.*, *Paypal/iZettle*, £250,000 for failure to comply with IEO (24 September 2019); *Nicholls' (Fuel Oils)/DCC Energy*, £146,000 for failure to comply with IEO (16 July 2019); *Vanilia/Washstation*, £120,000 for failure to comply with IEO (8 March 2019); *Ausurus/CuFe Investments*, £300,000 for failure to comply with IEO (20 December 2018).

source of competition. In such markets, it could be that any entrant with a credible strategy and route to funding is worth protecting". Dr. Coscelli strongly advocated in favour of broadening the merger review "to accept more uncertainty in their assessment of the counterfactual", by reviewing a merger not only with reference to current competitive conditions and "near-term market developments", but by considering the long-term future development of the firms involved.

The CMA's decision in Roche/Spark is also remarkable because the CMA considered Phase II R&D to be a "relatively advanced" stage of development that may evidence that a product has "a realistic potential of being commercialised within the foreseeable future".[7] The CMA even went so far as to consider Spark's Phase I trial products, stating that because Spark had already commissioned a follow-up study and was about to start an observational study for its Phase II product to recruit subjects for its Phase III trials, it would "consider it appropriate" to consider these products to be at a more advanced development stage.[8] This is in stark contrast to the approach taken by the European Commission which generally considers only pipeline products that are at least at Phase II or Phase III to be sufficiently advanced for inclusion in its competitive analysis.[9]

Concluding Remarks

The CMA's more creative use of the share of supply test and "purposive" enforcement of the Enterprise Act 2002 erode legal certainty for merging parties in two ways: First, by making it more difficult to predict the likelihood of CMA intervention in transactions lacking any real nexus to the UK market; and second, by the risk that the CMA will deploy novel analytical concepts such as "actual potential competition" to challenge acquisitions of "nascent competitors" .

As a result, merging parties will need to recognise the impact of a potential CMA merger inquiry early on. This will allow parties to prudently manage timing considerations, including the potential impact of an IEO, and to ensure smooth navigation through the CMA's review to successful completion.

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7 *See* paragraphs 92 and 99 of the CMA decision in Roche/Spark.

8 Footnote 3 to the table in paragraph 56 of the CMA decision in Roche/Spark.

9 *See*, *e.g.*, Case M.9294 BMS/Celgene [2019], paragraph 22; Case M.5476 *Pfizer/Wyeth* [2009], paragraph 35.

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CONTACTS

New York

Werner Federico Ahlers	+1 212 558 1623	ahlersw@sullcrom.com
Francis J. Aquila	+1 212 558 4048	aquilaf@sullcrom.com
Audra D. Cohen	+1 212 558 3275	cohena@sullcrom.com
H. Rodgin Cohen	+1 212 558 3534	cohenhr@sullcrom.com
Scott B. Crofton	+1 212 558 4682	croftons@sullcrom.com
Mitchell S. Eitel	+1 212 558 4960	eitelm@sullcrom.com
John Evangelakos	+1 212 558 4260	vangelakosj@sullcrom.com
Sergio J. Galvis	+1 212 558 4740	galviss@sullcrom.com
C. Andrew Gerlach	+1 212 558 4789	gerlacha@sullcrom.com
Matthew B. Goodman	+1 212 558 4995	goodmanm@sullcrom.com
Dustin F. Guzior	+1 212 558 4482	guziord@sullcrom.com
Brian E. Hamilton	+1 212 558 4801	hamiltonb@sullcrom.com
Steven L. Holley	+1 212 558 4737	holleys@sullcrom.com
Matthew G. Hurd	+1 212 558 3122	hurdm@sullcrom.com
Stephen M. Kotran	+1 212 558 4963	kotrans@sullcrom.com
Mark J. Menting	+1 212 558 4859	mentingm@sullcrom.com
Scott D. Miller	+1 212 558 3109	millersc@sullcrom.com
Keith A. Pagnani	+1 212 558 4397	pagnanik@sullcrom.com
George J. Sampas	+1 212 558 4945	sampasg@sullcrom.com
Melissa Sawyer	+1 212 558 4243	sawyerm@sullcrom.com
Alan J. Sinsheimer	+1 212 558 3738	sinsheimera@sullcrom.com
Krishna Veeraraghavan	+1 212 558 7931	veeraraghavank@sullcrom.com
Benjamin R. Walker	+1 212 558 7393	walkerb@sullcrom.com

Washington, D.C.		
Renata B. Hesse	+1 202 956 7575	hesser@sullcrom.com
Joseph J. Matelis	+1 202 956 7610	matelisj@sullcrom.com
Robert S. Risoleo	+1 202 956 7510	risoleor@sullcrom.com
Los Angeles		
Eric M. Krautheimer	+1 310 712 6678	krautheimere@sullcrom.com
Rita-Anne O'Neill	+1 310 712 6698	oneillr@sullcrom.com
Adam S. Paris	+1 310 712 6663	parisa@sullcrom.com
Alison S. Ressler	+1 310 712 6630	resslera@sullcrom.com
Palo Alto		
Scott D. Miller	+1 650 461 5620	millersc@sullcrom.com
Sarah P. Payne	+1 650 461 5669	paynesa@sullcrom.com
London		
John Horsfield-Bradbury	+44 20 7959 8491	horsfieldbradburyj@sullcrom.com
Jeremy B. Kutner	+44 20 7959 8484	kutnerj@sullcrom.com
Ben Perry	+44 20 7959 8477	perryb@sullcrom.com
Richard A. Pollack	+44 20 7959 8404	pollackr@sullcrom.com
Juan Rodríguez	+44 20 7959 8499	rodriguezja@sullcrom.com
Paris		
Olivier de Vilmorin	+33 1 7304 5895	devilmorino@sullcrom.com
Frankfurt		
Carsten Berrar	+49 69 4272 5506	berrarc@sullcrom.com
Krystian Czerniecki	+49 69 4272 5525	czernieckik@sullcrom.com
York Schnorbus	+49 69 4272 5517	schnorbusy@sullcrom.com
Brussels		
Michael Rosenthal	+32 2896 8001	rosenthalm@sullcrom.com
Tokyo		
Keiji Hatano	+81 3 3213 6171	hatanok@sullcrom.com
Hong Kong		
Garth W. Bray	+852 2826 8691	brayg@sullcrom.com
Kay Ian Ng	+852 2826 8601	ngki@sullcrom.com
Beijing		
Gwen Wong	+86 10 5923 5967	wonggw@sullcrom.com
Melbourne		
Waldo D. Jones Jr.	+61 3 9635 1508	jonesw@sullcrom.com
Sydney		
Waldo D. Jones Jr.	+61 2 8227 6702	jonesw@sullcrom.com